

# EXHIBIT 8

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UNITED STATES DISTRICT COURT DISTRICT OF MINNESOTA  ----- In Re: Bair Hugger Forced Air Warming Products Liability Litigation  This Document Relates To: All Actions MDL No. 15-2666 (JNE/FLM) -----  DEPOSITION OF DR. DANIEL SESSLER VOLUME I, PAGES 1 - 152 JANUARY 11, 2017  (The following is the deposition of DR. DANIEL SESSLER, taken pursuant to Notice of Taking Deposition, via videotape, at the Cleveland Clinic, P Building, Conference Room P77-013, 2070 East 90th Street, Cleveland, Ohio, commencing at approximately 10:11 o'clock a.m., January 11, 2017.)		I N D E X  EXHIBITS DESCRIPTION PAGE MARKED Ex 226 Excel spreadsheet of data, 3MBH00049711-3 39 227 E-mail string, 3MBH00024866 95 228 E-mail string, 3MBH01054232-4 121 229 E-mail with attachment, 3MBH01621689-95 123 230 E-mail, 3MBH01486024 125 231 E-mail string, 3MBH01534469-71 131 232 E-mail string, 3M00585482-3 143 233 E-mail, 3MBH00518536 145 234 Sessler deposition transcript dated November 20, 2015 150 235 Sessler deposition transcript dated July 9, 2015 150 236 Sessler deposition transcript dated May 27, 2015 150	
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1 APPEARANCES: 2 On Behalf of the Plaintiffs: 3 Jan M. Conlin 4 CIRESI CONLIN L.L.P. 5 225 South 6th Street, Suite 4600 6 Minneapolis, Minnesota 55402 7 8 Gabriel Assaad 9 KENNEDY HODGES 10 4409 Montrose Boulevard, Suite 200 11 Houston, Texas 77006 12 On Behalf of Defendants: 13 Corey L. Gordon and Peter J. Goss 14 BLACKWELL BURKE P.A. 15 432 South Seventh Street, Suite 2500 16 Minneapolis, Minnesota 55415 17 18 On Behalf of the Deponent: 19 Sandra M. DiFranco 20 Cleveland Clinic Law Department 21 2070 East 90th Street 22 Cleveland, Ohio 44195 23 24 25		1 P R O C E E D I N G S 2 (Witness sworn.) 3 DR. DANIEL SESSLER 4 called as a witness, being first duly sworn, 5 was examined and testified as follows: 6 ADVERSE EXAMINATION 7 BY MS. CONLIN: 8 Q. Good morning, Dr. Sessler. We've not met 9 before; correct? 10 A. Correct. 11 Q. Okay. I represent plaintiffs in an action 12 that's been brought against 3M involving the Bair 13 Hugger device. Do you understand that? 14 A. Yes. 15 Q. Okay. And you, in fact, were deposed a 16 number of times in connection with this Bair Hugger 17 device in connection with the Walton and Johnson Texas 18 litigations; correct? 19 A. I was deposed a number of times. I am not 20 sure what it was about. 21 Q. Okay. But you did -- 22 You were deposed three times as it relates 23 to your work and advice regarding the Bair Hugger 24 device; correct? 25 A. Correct.	

1 (Pages 1 to 4)

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<p>1 DIN 1946 was chosen because it is objective and more</p> <p>2 rigorous than the United States standard. Do you see</p> <p>3 that?</p> <p>4 <b>A. No. I'm in a different place.</b></p> <p>5 Q. It's right here.</p> <p>6 <b>A. Okay. Now I'm with you.</b></p> <p>7 <b>Yes.</b></p> <p>8 Q. Okay. Do you --</p> <p>9 Now the DIN 1946 standard governs laminar</p> <p>10 flow rooms --</p> <p>11 <b>A. Yes.</b></p> <p>12 Q. -- in Europe; correct?</p> <p>13 <b>A. I believe so.</b></p> <p>14 Q. Do you know whether that D -- DIN standard</p> <p>15 forbids the use of forced-air warming in laminar flow</p> <p>16 rooms in the EU?</p> <p>17 <b>A. At the time we wrote this paper, I'm pretty</b></p> <p>18 <b>sure it did not.</b></p> <p>19 Q. And what's that based on?</p> <p>20 <b>A. Well I did look at the standard at one</b></p> <p>21 <b>point.</b></p> <p>22 Q. So at the time you submitted this paper, you</p> <p>23 thought that the -- that forced-air warming could be</p> <p>24 used under the DIN standard in the EU; correct?</p> <p>25 <b>A. That was certainly my impression, yes.</b></p>	<p>1 Q. And how do you know that, doctor?</p> <p>2 <b>A. As far as I know, all forced-air warmers</b></p> <p>3 <b>contain relatively good filters.</b></p> <p>4 Q. And you're making the assumption that the 3M</p> <p>5 one does as well; correct?</p> <p>6 <b>A. Correct.</b></p> <p>7 Q. If I told you the filtration efficiency was</p> <p>8 53 percent, would that surprise you?</p> <p>9 MR. GORDON: Object to the form of the</p> <p>10 question.</p> <p>11 <b>A. Yes.</b></p> <p>12 Q. Okay. I'm going to hand you, Dr. Sessler,</p> <p>13 what's been previously marked as Deposition Exhibit</p> <p>14 66. It's actually a two-page document, so I'd ask you</p> <p>15 to start on the second page and then read up to the</p> <p>16 first.</p> <p>17 Have you had a chance to read it?</p> <p>18 <b>A. Yes.</b></p> <p>19 Q. Okay. Were you aware that Arizant and 3M</p> <p>20 were getting calls from the field from users of the</p> <p>21 Bair Hugger that were concerned about infectious</p> <p>22 pathogens that were being found in the machines?</p> <p>23 MR. GORDON: Object to the form of the</p> <p>24 question, lack of foundation.</p> <p>25 <b>A. No.</b></p>
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<p>1 Q. Now you also write on the right-hand side of</p> <p>2 this second page, quote, "The forced air blower was</p> <p>3 positioned on the floor at the volunteer's left side,</p> <p>4 near where the anesthesiologist would normally sit</p> <p>5 during surgery." Do you see that?</p> <p>6 <b>A. Yes.</b></p> <p>7 Q. Do you know if these were new machines or</p> <p>8 used machines?</p> <p>9 <b>A. I don't know.</b></p> <p>10 Q. That wasn't something that was of interest</p> <p>11 or import to you?</p> <p>12 <b>A. No. Because as far as I know, age of the</b></p> <p>13 <b>machine is not relevant to the question here.</b></p> <p>14 Q. You don't know whether the machine --</p> <p>15 Well you understand the air intake is at the</p> <p>16 bottom of the machine, correct, on the floor?</p> <p>17 <b>A. I'll take your word for that.</b></p> <p>18 Q. Okay. Have you ever examined the machine?</p> <p>19 <b>A. I've used these machines thousands of times,</b></p> <p>20 <b>but I couldn't testify to where the air intake is.</b></p> <p>21 Q. Okay. Have you asked 3M or Arizant for any</p> <p>22 information regarding whether the air intake absorbs</p> <p>23 bacteria near the floor of the OR?</p> <p>24 <b>A. No, I didn't, because it's filtered in the</b></p> <p>25 <b>machine. What comes out is sterile.</b></p>	<p>1 Q. Okay. Do you see at the top there where Mr.</p> <p>2 Van Duren says, "Remove and discard the filter (in the</p> <p>3 biohazardous waste)?" Do you see that?</p> <p>4 <b>A. Yes.</b></p> <p>5 Q. Now if the machine that you were using in</p> <p>6 surgery was contaminated with a microorganism, let's</p> <p>7 say MRSA, would you want to know whether that filter</p> <p>8 was going to filter that pathogen properly?</p> <p>9 MR. GORDON: Object to the form of the</p> <p>10 question.</p> <p>11 MS. DIFRANCO: Go ahead.</p> <p>12 <b>A. It's a two-part question.</b></p> <p>13 Q. In what way?</p> <p>14 <b>A. Can -- can we break this apart? If -- if a</b></p> <p>15 <b>machine's contaminated and --</b></p> <p>16 Q. Well all right, that's -- that's a fair</p> <p>17 correction. Let me back up.</p> <p>18 If a machine was contaminated with MRSA,</p> <p>19 would that be something as an anesthesiologist you</p> <p>20 would want to know before you decided to use that</p> <p>21 machine on a patient?</p> <p>22 <b>A. Sure.</b></p> <p>23 Q. Okay. And if --</p> <p>24 And would you also want to know whether the</p> <p>25 filter was able to prevent MRSA or some other pathogen</p>

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<p>1       <b>A. Yes. That's the average, right? It --</b>  2       Q. Well it says at the top "Off."  3       <b>A. No, it's -- it's raw data. Okay. Thank</b>  4       <b>you.</b>  5       Q. Okay? And then with the Bair Hugger at  6       ambient temperature, the particle count over the  7       hypothetical surgical site was 57; correct?  8       <b>A. Right.</b>  9       Q. So that would be a two-times increase; is  10      that right?  11      <b>A. Yes.</b>  12      Q. Okay. And then if you turn the Bair Hugger  13      on to warm, the particle count over the surgical site  14      is 349 particles; correct?  15      <b>A. Yes.</b>  16      Q. Okay. <b>So that's about a thousand-percent</b>  17      <b>increase between off and the Bair Hugger on warm;</b>  18      <b>correct?</b>  19      <b>A. Yes. It's about a factor of 10.</b>  20      Q. Okay. About 12 times as many particles;  21      correct, doctor?  22      <b>A. Right.</b>  23      Q. Okay.  24      <b>A. If you look at the -- the other one -- the</b>  25      <b>other run, though, it has much less effect. Also, you</b></p>	<p>1       <b>A. In this run it had a very small effect, in</b>  2       <b>the other run it had no effect.</b>  3       Q. Okay. So how is it that you can say in the  4       title of your paper that forced-air warming does not  5       worsen air quality in laminar flow operating rooms  6       when at least some of the -- well all of the runs  7       showed at least some difference between the Bair  8       Hugger off and the Bair Hugger on?  9       MR. GORDON: Object to the form of the  10      question.  11      <b>A. The average performance effect with ambient</b>  12      <b>versus warm was 4.8 versus 4.8 in one test, it was 3.2</b>  13      <b>versus 3.5 in another, it was 4.8 versus 4.8 in the</b>  14      <b>third, and it was 4.7 versus 4.6. There -- there's no</b>  15      <b>difference there.</b>  16      Q. Well that -- that's the PE, the protective  17      effect; correct?  18      <b>A. Yes.</b>  19      Q. Okay. And the protective effect went down  20      on average.  21      <b>A. It was unchanged. There -- there's no</b>  22      <b>important change here. Those numbers are virtually</b>  23      <b>identical.</b>  24      Q. You don't think that a change in the  25      protective effect from 4.0 to 3.2 makes a difference?</p>
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<p>1       <b>need to look at the average; it's not fair to pick one</b>  2       <b>run.</b>  3       Q. If --  4       Well, it's got a p-value of .06, correct,  5       for off?  6       <b>A. Yeah. But that's the average. You're</b>  7       <b>looking at one run.</b>  8       Q. Right. Well you only did five runs;  9       correct?  10      <b>A. Yes. But you have to look at all five of</b>  11      <b>them.</b>  12      Q. Okay. Would you agree with me five runs is  13      a pretty small sample?  14      MR. GORDON: Object to the form of the  15      question.  16      <b>A. No.</b>  17      Q. Why?  18      <b>A. Because this is a mechanical sort of setup</b>  19      <b>and you should get about the same result each time.</b>  20      Q. Well it has --  21      Looking at this raw data, the use of the  22      Bair Hugger does have an effect on the particulate  23      count over the hypothetical surgery site; correct?  24      MR. GORDON: Object to the form of the  25      question.</p>	<p>1       MR. GORDON: Object to the form of the  2       question.  3       <b>A. No. And I especially don't think a</b>  4       <b>difference from 4.8 to 4.8 or from 4.8 to 4.8 in the</b>  5       <b>other study makes a difference.</b>  6       Q. Why didn't you --  7       Why did you pool the data from Amersfoort  8       and Utrecht?  9       <b>A. Oh. Why wouldn't I?</b>  10      Q. Did you make that decision?  11      <b>A. Probably.</b>  12      Q. Okay. Do you think that a physician would  13      want to know that, with use of the 635 underbody  14      blanket, the particulate count went up 12-fold with  15      use of the Bair Hugger?  16      MR. GORDON: Object to the form of the  17      question.  18      MS. DIFRANCO: I'll object. You're asking  19      what other physicians would want to know?  20      Q. Would you want to know?  21      <b>A. That was one run. That's not an accurate</b>  22      <b>characterization of this study result, not even</b>  23      <b>slightly accurate.</b>  24      Q. Well it went up --  25      If you look at just the 635, the underbody</p>

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<p style="text-align: right;">Page 61</p> <p>1 Q. Okay. Now in the next paragraph you say,</p> <p>2 "What clinicians will want to see is basically</p> <p>3 particle counts under three test circumstances (Off,</p> <p>4 Ambient, and Warm)." Do you see that?</p> <p>5 A. Yup.</p> <p>6 Q. Then you write, "Any substantial increase</p> <p>7 will still concern them and basically validate Scott's</p> <p>8 point that forced-air warming increases risk. We can</p> <p>9 try to convince them that the increase isn't important</p> <p>10 or that operating rooms still meet DIN standards, but</p> <p>11 that will be a bit tricky." Do you see that?</p> <p>12 A. Yup.</p> <p>13 Q. You knew that physicians would want to see</p> <p>14 whether, in an individual case such as the 65 -- or</p> <p>15 635 testing in Amersfoort, that there was a</p> <p>16 substantial increase in particulates; correct?</p> <p>17 A. No, that's not what that means.</p> <p>18 Q. Okay. What -- what -- what were you saying</p> <p>19 there?</p> <p>20 A. That first it --</p> <p>21 Note the third paragraph where I correct the</p> <p>22 statistical approach. You need to look at all the</p> <p>23 data; you can't just pick one piece of data, one line,</p> <p>24 one run, and say this characterizes the results.</p> <p>25 Q. Okay.</p>	<p style="text-align: right;">Page 63</p> <p>1 best to consider the hospitals together since that</p> <p>2 isn't really a factor of interest; and the cover type</p> <p>3 could be unpaired." Do you see that?</p> <p>4 A. Uh-huh. Yes.</p> <p>5 Q. And in fact what you were describing there</p> <p>6 is rather than show the results from the two hospitals</p> <p>7 separately, you were going to group them together for</p> <p>8 the purposes of the paper; right?</p> <p>9 A. Yes, because it -- that's the way it should</p> <p>10 have been done. That's -- that's the correct way of</p> <p>11 handling these data.</p> <p>12 Q. Why is it the correct way of handling these</p> <p>13 data?</p> <p>14 A. Because the two hospitals together</p> <p>15 characterize the general case better than either</p> <p>16 hospital alone.</p> <p>17 Q. Well you know that ORs are different; right?</p> <p>18 A. Sure.</p> <p>19 Q. Okay. That can be a confounding factor;</p> <p>20 right?</p> <p>21 A. Could be.</p> <p>22 MR. GORDON: Object to the form of the</p> <p>23 question.</p> <p>24 Q. Could be a confounding factor.</p> <p>25 Did you do any investigation as to whether</p>
<p style="text-align: right;">Page 62</p> <p>1 A. That's -- that's called data selection; it's</p> <p>2 a type of research fraud.</p> <p>3 Q. Would you agree --</p> <p>4 A. You have to look at all the data.</p> <p>5 Q. Would you agree with me that any substantial</p> <p>6 increase would concern clin -- clinicians?</p> <p>7 A. Average increase, not -- not results from</p> <p>8 one run and one circumstance.</p> <p>9 Q. Would you agree with me that any substantial</p> <p>10 increase would concern clinicians?</p> <p>11 MR. GORDON: Object to the form of the</p> <p>12 question, also lack of foundation.</p> <p>13 A. Any substantial increase in average values</p> <p>14 over all conditions would concern people.</p> <p>15 Q. Okay. And then you say in the third</p> <p>16 paragraph, "Possibly the best statistical approach</p> <p>17 would be an ANOVA with cover type...;" correct?</p> <p>18 A. Yes.</p> <p>19 Q. And that's in fact what you guys have ended</p> <p>20 up doing; correct?</p> <p>21 A. Correct.</p> <p>22 Q. Okay. And ANOVA is basically analysis of</p> <p>23 variance; right?</p> <p>24 A. Yes.</p> <p>25 Q. And then you say, "But perhaps it would be</p>	<p style="text-align: right;">Page 64</p> <p>1 the machine that was used in Amersfoort might have</p> <p>2 been a used one versus a new one?</p> <p>3 A. No.</p> <p>4 Q. Or that there was different protocols for</p> <p>5 how they clean the OR?</p> <p>6 A. No. But it's not relevant to this study,</p> <p>7 which used artificial particles. This had nothing to</p> <p>8 do with bacteria.</p> <p>9 Q. Well I think we've already established you</p> <p>10 don't know whether the Bair Hugger sucks in</p> <p>11 particulates from off the floor and spews them out</p> <p>12 into the surgical site; right?</p> <p>13 MR. GORDON: Object to the form of the</p> <p>14 question.</p> <p>15 A. I don't think that's relevant to this study</p> <p>16 where there are 20 million particles floating around</p> <p>17 that are deliberately introduced.</p> <p>18 Q. So it wouldn't be of clinical interest to</p> <p>19 you.</p> <p>20 A. You -- you're confusing two different</p> <p>21 circumstances. One is whether forced-air warmers pick</p> <p>22 up bacteria, retain bacteria or somehow eject</p> <p>23 bacteria. If they do, that's a problem. A second</p> <p>24 issue, which is what this paper is about, is whether</p> <p>25 warm air interferes with the laminar flow column. Has</p>

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<p>1 <b>nothing to do with bacteria.</b></p> <p>2 Q. Okay. And you -- you --</p> <p>3 I think we've established this. You're not</p> <p>4 an expert on laminar flow or how particulates move in</p> <p>5 the environment; right?</p> <p>6 <b>A. I'm not.</b></p> <p>7 Q. So you -- you basic --</p> <p>8 Did you ask anybody why it was that the</p> <p>9 Amersfoort data appeared so different in terms of the</p> <p>10 particulate counts?</p> <p>11 MR. GORDON: Object to the form of the</p> <p>12 question.</p> <p>13 <b>A. I don't remember.</b></p> <p>14 Q. Was it of interest to you?</p> <p>15 <b>A. Absolutely.</b></p> <p>16 Q. What do you recall doing in connection with</p> <p>17 that data?</p> <p>18 <b>A. When you do multicenter studies, it's</b></p> <p>19 <b>absolutely routine and normal for the results to</b></p> <p>20 <b>differ in the various centers. You -- you expect that</b></p> <p>21 <b>just by random motion. And it's also true that the</b></p> <p>22 <b>centers are truly different; they have different</b></p> <p>23 <b>operating rooms, different anesthesia, different</b></p> <p>24 <b>protocols, so you expect real differences among sites</b></p> <p>25 <b>in a multicenter study. But you do a multicenter</b></p>	<p>1 <b>A. Yes.</b></p> <p>2 Q. And then Dr. Olmstead took a crack at it; is</p> <p>3 that right?</p> <p>4 <b>A. Yes.</b></p> <p>5 Q. And then you edited it; correct?</p> <p>6 <b>A. "Edited" is a generous term. Virtually</b></p> <p>7 <b>every word in the published manuscript was mine.</b></p> <p>8 Q. I've handed you, Dr. Sessler, what's been</p> <p>9 previously marked as Deposition Exhibit 79, which is a</p> <p>10 marked-up draft of your study which eventually was</p> <p>11 published and has been previously marked as (Belani)</p> <p>12 Exhibit 16; correct?</p> <p>13 <b>A. Yes.</b></p> <p>14 Q. Okay. And you were part of this editing</p> <p>15 process; correct?</p> <p>16 <b>A. Yes.</b></p> <p>17 Q. If we can take a look at draft -- the draft</p> <p>18 page seven, which bears Bates number 50592, and if we</p> <p>19 can look at the middle paragraph starting with "We</p> <p>20 found..."</p> <p>21 <b>A. Yes.</b></p> <p>22 Q. Okay. Midway down there there is a section</p> <p>23 which in this draft reads, "There were noticeable</p> <p>24 differences in the results between the two operating</p> <p>25 rooms, probably the result of small differences in</p>
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<p>1 <b>study to enhance generalizability. You take all the</b></p> <p>2 <b>results you have and you put them together and you</b></p> <p>3 <b>present the average because that best characterizes</b></p> <p>4 <b>what you know, and that's what we did here.</b></p> <p>5 Q. And in this case you did five samples, five</p> <p>6 runs five minutes each in two hospitals; correct?</p> <p>7 <b>A. Yes.</b></p> <p>8 Q. And in fact you noted here that there were</p> <p>9 only five measurements; right?</p> <p>10 <b>A. Correct.</b></p> <p>11 Q. So you're standing behind your proposition</p> <p>12 that this is not an under -- underpowered study;</p> <p>13 correct?</p> <p>14 MR. GORDON: Object to the form of the</p> <p>15 question.</p> <p>16 <b>A. Correct.</b></p> <p>17 Q. Could pooling the data from Amersfoort and</p> <p>18 Utrecht confound the data?</p> <p>19 <b>A. No.</b></p> <p>20 Q. Why not?</p> <p>21 <b>A. "Confounding" has a specific meaning, has to</b></p> <p>22 <b>be something that's related to exposure and outcome.</b></p> <p>23 <b>I don't see how pooling induces confounding.</b></p> <p>24 Q. Now I think we talked about this before, but</p> <p>25 <b>Gary Hansen did the first draft; is that right?</b></p>	<p>1 draping around the OR table, and also perhaps due to</p> <p>2 differences in the laminar flow systems." Do you see</p> <p>3 that?</p> <p>4 <b>A. I do.</b></p> <p>5 Q. And there was a deleted box beside that, and</p> <p>6 what was deleted is "The significantly higher counts</p> <p>7 seen with the blanket model 635 reflected conditions</p> <p>8 at OR Amersfoort" or "A..." Do you see that?</p> <p>9 <b>A. I see it, yes.</b></p> <p>10 Q. Okay. <b>Who made the decision to delete from</b></p> <p>11 <b>this transcript that there had been significantly</b></p> <p>12 <b>higher counts seen with the underbody blanket at the</b></p> <p>13 <b>Amersfoort hospital?</b></p> <p>14 <b>A. Well, whoever edited the document.</b></p> <p>15 Q. Do you know if that was Mr. Hansen at 3M?</p> <p>16 <b>A. I have no idea who was editing at this</b></p> <p>17 <b>point.</b></p> <p>18 Q. Okay. Was that something that you had</p> <p>19 drafted originally, that you had found significantly</p> <p>20 higher counts seen with the blanket model 635 in</p> <p>21 Amersfoort?</p> <p>22 <b>A. I'm not sure I understand the question.</b></p> <p>23 Q. My question is: Do you know whether you</p> <p>24 were the person who originally put in the draft that</p> <p>25 there had been significantly higher counts seen with</p>

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<p>1       <b>A. I don't know. I'm sorry, I haven't read</b>  2       <b>this yet.</b>  3       Q. If you look at the page before, in five  4       there's a heading, and would this have been a  5       presentation that you made at this meeting, or are  6       these a summary of the points that you made at the  7       meeting regarding your proposed study in China?  8       <b>A. It -- I believe it was a presentation.</b>  9       Q. Okay. And then at the --  10       If we look at the two bullet points at the  11       top of page six, there's a notation, "Kurz 1996 SSI  12       paper limitations," and it says, "only 200 patients,  13       mostly superficial infections with few clinical  14       consequences (we should focus on deep tissue/organ  15       SSIs), the factor of 3 risk increase is not plausible  16       (30 percent or so is more likely)." Do you see that?  17       <b>A. Yes.</b>  18       Q. Was that information that you presented  19       during this advisory meeting at 3M?  20       <b>A. Apparently.</b>  21       Q. Okay. Then you went on to say, "Melling  22       paper seriously flawed: only 420 low risk patients,  23       infection was not defined, core temperature not  24       recorded (!)" See that?  25       <b>A. Yes.</b></p>	<p>1       speed and leave you exposed. Large outcomes studies  2       are needed to take the place of the old studies."  3       Is that something that you recall mentioning  4       to 3M at this meeting?  5       <b>A. No.</b>  6       Q. Okay. Do you deny that you said it?  7       <b>A. Oh, no. It looks like I did, I just don't</b>  8       <b>recall it.</b>  9       Q. Okay. Then if we take a look at page seven,  10       midway down it's "Hooper/laminar flow in hip/knee  11       replacements." Do you recall what that's about?  12       <b>A. Only vaguely.</b>  13       Q. Okay. What is the Hooper/laminar flow in  14       hip/knee replacements?  15       <b>A. I know --</b>  16       <b>I don't remember the study, so I know</b>  17       <b>nothing except what I'm reading right here, which is</b>  18       <b>not enough for me to discuss it.</b>  19       Q. Okay. And do you see that Al Van Duren  20       said, "Shows laminar flow is not effective. But  21       potentially could be interpreted to mean that  22       forced-air warming disturbs laminar flow, causing  23       laminar flow not to work." Do you recall him saying  24       that?  25       <b>A. No.</b></p>
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<p>1       Q. Do you agree that the Melling paper is  2       seriously flawed, as you stated to 3M?  3       <b>A. Yes.</b>  4       Q. Okay. And do you agree with me that you  5       told 3M that the Kurz 1996 SSI paper has limitations  6       and you identified them to 3M?  7       <b>A. All papers have limitations.</b>  8       Q. Okay. Now if we go down --  9       Well, and you in fact mentioned these  10       limitations on the Kurz study to 3M at this meeting as  11       reflected in these notes; correct?  12       <b>A. Yes.</b>  13       Q. Okay. Then we go down and it's got sort  14       of a -- almost like a Q&amp;A. It says "Question: why  15       should 3M fund a study to show risks associated with  16       hypothermia when there is already broad acceptance of  17       current evidence?"  18       And then there's a "DS." Is that referring  19       to you?  20       <b>A. I assume.</b>  21       Q. Okay. It says, "the threat to 3M is that  22       the old studies will begin to be discredited."  23       Is that a reference to Melling and Kurz?  24       <b>A. Probably.</b>  25       Q. Okay. "Once this begins it will pick up</p>	<p>1       Q. And if we take a look on the last page, page  2       eight, it says, "Discussion of new aerobiology study  3       to counter the 'BAIR' misinformation." And it says,  4       "GH" -- I assume that's Gary Hansen -- "presented  5       study proposal. Board supported the idea."  6       Then it goes on to say "DS" -- which is  7       you -- "Host defense protects against SSI much more  8       than sterile ORs and external conditions. This study  9       would take the wind out of the 'BAIR' argument. That  10       is the only reason to do it."  11       Do you see that there?  12       <b>A. Yes.</b>  13       Q. Does that sound like a statement you would  14       have made?  15       <b>A. I -- I don't really know what the new</b>  16       <b>aerobiology study is, so I don't think I can comment</b>  17       <b>here.</b>  18       Q. Okay. We did talk today a little bit about  19       your view that the host defense protects against  20       surgical-site infections; right?  21       <b>A. Host defense is absolutely critical.</b>  22       Q. Okay. But you don't know whether --  23       Well let me ask it this way: What is the  24       host defense if a bacterium lands on an implant, like  25       a knee?</p>

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<p>1 Q. Okay. "In summary, mean intraoperative TWA 2 core temperatures were no different, and significantly 3 noninferior, with underbody resistive heating than 4 upper-body forced-air warming. Underbody resistive 5 heating may be an alternative to forced-air warming." 6 That's what you concluded in this study that 7 was published in 2011; am I right? 8 <b>A. Yes.</b> 9 Q. And have you seen any counter evidence to -- 10 that would undermine the conclusions that you reached 11 in this study? 12 <b>A. No.</b> 13 <b>(Exhibit 230 was marked for</b> 14 <b>identification.)</b> 15 BY MS. CONLIN: 16 Q. I've handed you, Dr. Sessler, what's been 17 marked as Exhibit 230, which is an e-mail exchange 18 between Niya Johnson and Michelle Hulse Stevens with a 19 copy to Al Van Duren. Do you see that? 20 <b>A. Yes.</b> 21 Q. Dated November 18th, 2015, "Subject: BMW 22 refocus: pre-warming." Do you see that? 23 <b>A. Yes.</b> 24 Q. And it says, "Michelle, 25 "I'd like to extend you an invitation to</p>	<p>1 (Recess taken.) 2 BY MS. CONLIN: 3 Q. I've handed you, Dr. Sessler, what's been 4 previously marked as Deposition Exhibit 222. It 5 starts, actually, with an e-mail from you on the third 6 page, so you might want to start on the third page 7 and -- and read up. 8 <b>A. Oh, okay.</b> 9 <b>Okay.</b> 10 Q. Okay. If we can take a look at the third 11 page bearing Bates 541796 of Exhibit 222 first, you 12 write to a number of people at 3M; am I right? 13 <b>A. Yes.</b> 14 Q. About a -- 15 Sounds to me like there was a key-opinion- 16 leader meeting in Washington. Was that in connection 17 with your work for 3M or was that just on the SCIP-10 18 protocol in general? 19 <b>A. I don't know.</b> 20 Q. Okay. It says, "One of the points 21 Andrea" -- 22 Who is Andrea? 23 <b>A. Probably Andrea Kurz.</b> 24 Q. Okay. 25 -- "Andrea Kurz and I tried to make at the</p>
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<p>1 join the BMW team call" -- or "team on a call with two 2 KOLs and experts on pre-warming Dr. Brauer and Dr. 3 Sessler." Do you see that? 4 <b>A. Yes.</b> 5 Q. What -- what is the BMW? 6 MR. GORDON: Objection, lack of foundation. 7 <b>A. I haven't a clue.</b> 8 Q. Okay. Are you working with 3M on a 9 prewarming project? 10 <b>A. No.</b> 11 Q. It says "on pre-warming," do you see that, 12 "call with two KOLs and experts on pre-warming Dr. 13 Brauer and Dr. Sessler?" 14 <b>A. I see that.</b> 15 Q. Okay. But you're not aware of any work 16 you're doing with 3M on prewarming right now? 17 <b>A. We -- we are not doing work with 3M on</b> 18 <b>prewarming now.</b> 19 Q. Okay. Do you know if BMW refers to Bair 20 Mobile Warming? 21 MR. GORDON: Objection, lack of foundation. 22 <b>A. No, I don't. I have no idea what it means.</b> 23 Q. Okay. 24 THE REPORTER: We have to change disks. Off 25 the record, please.</p>	<p>1 KOL meeting in Washington is that the evidence for 2 hypothermia-related complications mostly does not meet 3 current research guidelines for reliability and that 4 previous studies were done with much larger 5 temperature differences than are currently allowed." 6 What do you mean by that? 7 <b>A. The major trials showing that hypothermia</b> 8 <b>causes complications mostly compared temperatures of</b> 9 <b>about 36.5 to about 34.5; no patients now are allowed</b> 10 <b>to get to 34.5.</b> 11 Q. And then in the third paragraph you say, 12 "The writing is on the wall. Without new evidence of 13 harm from current levels of hypothermia, SCIP-10 is 14 unlikely to survive into the next version of pay-for- 15 performance measures." 16 What's that a reference to? 17 <b>A. SCIP-10 is Surgical Care Improvement</b> 18 <b>Project, 10 was one of many measures defining quality</b> 19 <b>criteria, and warming and maintaining normothermia was</b> 20 <b>one of them.</b> 21 Q. And -- 22 <b>A. That -- that -- that's what number 10 was.</b> 23 Q. And you were involved in that, right, that 24 proposal? 25 <b>A. I -- I was -- I was somewhat involved in</b></p>

32 (Pages 125 to 128)